Section 3 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.
There is no prior submission for the devices.

The assigned 510(K) number is K130947.

3.1 Submitter Information

OCT 0 3 2013

Manufacturer Name and Address:
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Date Prepared: April 27, 2013

3.2 Proposed Device Information

Device Common Name: Pulse Oximeter
Device Trade/Proprietary Name: Fingertip Pulse Oximeter
Model: MD300C1/MD300C2/MD300CF3/MD300CF61/MD300C61/MD300C63
Classification Name: Oximeter
Regulation Number: 870.2700
Product Code: DQA
Class: II
Panel: Anesthesiology

3.3 Predicate Device

Model 9550 Onyx® II Finger Pulse Oximeter
K-number: K051107
Product Code: DQA
Indications for Use: The Nonin® Onyx® II Model 9550 Finger Pulse Oximeter is a small, lightweight portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It is

intended for spotchecking of adult and pediatric patients on fingers (other than the thumb) between 0.3 - 1.0 inch (0.8 - 2.5 cm) thick. The index finger is the recommended site.

Manufactured by:

Nonin Medical, Inc.
13700 1st Ave. N.
Plymouth, MN 55441-5443

3.4 Device Description

The proposed devices of Fingertip Pulse Oximeters MD300C series are fingertip devices, which can display SpO_2 and pulse rate value.

The proposed devices consist of detector and emitter LED, signal amplify unit, CPU, display unit and power unit.

The pulse oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The wavelength of one light source is 660 nm, which is red light; the other is 940 nm, which is infrared light.

Skin, bone, tissue, and venous vessels normally absorb a constant amount of light over time. The photodetector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2.

The power sources of the proposed devices are 2 AAA alkaline batteries. All of the proposed devices have low battery voltage indicator function and all of the proposed devices will automatically power off when there is no signal for longer than 8 seconds.

The proposed devices of MD300CF3 and MD300CF61 have pulse rate tone modulation function. The function of pulse rate tone modulation is that the device can make a sound of Di-Di-Di to reflect pulse rate in real time.

The proposed devices are not for life-supporting or life-sustaining, not for implant. The devices or transducers are not sterile and the transducers are reusable and do not need sterilization or re-sterilization. The devices are for prescription. The devices do not contain drug or biological products.

The Fingertip Pulse Oximeters MD300C series share the same measurement principle and oximeter sensor and oxygen saturation module and power supply. The indented target population and use environment of the Fingertip Pulse Oximeters MD300C series are the same.

The devices are software-driven and the software validation is provided in Section of Software

The differences between each model of the proposed devices are shown the table 3-1

Table3-1

		MD300C1	MD300C2	MD300CF3	MD300CF61	MD300C61	MD300C63
Display Range	**SpO_2**	0-99%	0-100%	0-100%	0-100%	0-99%	0-100%
	PR	0~254BPM	0~254BPM	0~254BPM	0~254BPM	0~254BPM	0~254BPM
Measurement Range	**SpO_2**	70%-99%	70%-100%	70%-100%	70%-100%	70%-99%	70%-100%
	PR	30~235BPM	30~235BPM	30~235BPM	30~235BPM	30~235BPM	30~235BPM
Accuracy	**SpO_2**	70%-99%: ±2%; 0%-69%: no definition	70%-100%: ±2%; 0%-69%: no definition	70%-100%: ±2%; 0%-69%: no definition	70%-100%: ±2%; 0%-69%: no definition	70%-99%: ±2%; 0%-69%: no definition	70%-100%: ±2%; 0%-69%: no definition
	PR	30~99BPM : ±2BPM 100~235BPM: ±2%	30~99BPM : ±2BPM 100~235BPM: ±2%	30~99BPM : ±2BPM 100~235BPM: ±2%	30~99BPM : ±2BPM 100~235BPM: ±2%	30~99BPM : ±2BPM 100~235BPM: ±2%	30~99BPM : ±2BPM 100~235BPM: ±2%
Resolution	**SpO_2**	1%	1%	1%	1%	1%	1%
	PR	1BPM	1BPM	1BPM	1BPM	1BPM	1BPM
Display Screen		LED	OLED	OLED	OLED	LED	OLED
Pulse rate tone modulation function		N	N	Y	Y	N	N
The shape and size of shell		Although the proposed devices have different appearances, their sizes are similar. Please see the pictures of each model of the proposed device for the differences in appearance.					

3.5 Comparison list of the technological characteristics

Table 3-2 Comparison Table

Comparison Elements	**Proposed Device**	**predicate Device**
Device Name	Fingertip Pulse Oximeter MD300C series	Finger Pulse Oximeter（K051107）
Model	MD300C series: MD300C1/MD300C2/MD300CF3 /MD300CF61MD300C61/MD300C63	Onyx® II Model 9550
Regulation No.	21 CFR 870.2700	21 CFR 870.2700
Classification	II	II
Classification Name	Oximeter	Oximeter
Product Code	DQA	DQA
Indications for Use	The Fingertip Pulse Oximeters, MD300C series, are portable, non-invasive devices intended for spot checking of arterial hemoglobin oxygen saturation (SpO_2) and pulse rate of adult and pediatric patient at hospital (including clinical use in internist/surgery, Anesthesia, and intensive care units).'	The Nonin® Onyx® II Model 9550 Finger Pulse Oximeter is a small, lightweight portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It is intended for spotchecking of adult and pediatric patients on fingers (other than the thumb) between 0.3 - 1.0 inch (0.8 - 2.5 cm) thick. The index finger is the recommended site.
Comparison Statement	**The proposed devices have the same indications for use and classification.**	
Components	The applicant device consists of detector and emitter LED, signal amplify unit, CPU, data display unit and power unit	photo detector, LED, signal amplify unit, CPU, display unit and power unit

Design Principle		Skin, bone, tissue, and venous vessels normally absorb a constant amount of light over time. The photo detector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO_2.	Measure the absorption of red and infrared (IR) light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.
Measurement wavelength	Red	660nm	660nm
	Infrared	940nm	910nm
Comparison Statement		**The proposed devices have the same design principle and similar components.**	
Device Specification	Display Type	LED: MD300C1 MD300C61	LED
		OLED: MD300C2 MD300CF3 MD300CF61 MD300C63	
	Working time	Work for 30 hours continuously	Approximately 21 hours of continuous operation
	Power supply	2*AAA	2*AAA
	Display Data	SpO_2、PR	SpO_2、PR
	SpO_2 display range	0-99%: MD300C1、MD300C61	0-100%
		0-100%: MD300C2、MD300CF3、MD300C63、MD300CF61	
	SpO_2 Accuracy	70%-99% ±2%; 0-69% no definition: MD300C1、MD300C61	±2% (70-100%)
		70%-100% ±2%; 0-69% no definition: MD300C2、MD300CF3、MD300C63、MD300CF61	

	SpO_2 resolution		1%	1%
	PR Display Range		0-254bpm	18-321bpm
	PR Accuracy		±2bpm（30-99bpm）and 2%（100-235bpm）	±3% (20-250 BPM)
	PR resolution		1bpm	1bpm
	Operating temperature		5℃～40℃	0℃～40 ℃
	Relative humidity		≤80% (operating) ≤93% (storage)	10% ~ 90% (operating) 10% ~ 95% (storage)
	Atmosphere pressure		86kPa～106kPa	Up to 40,000 feet
	pulse rate tone modulation function		Available：MD300CF3、MD300CF61	Not Available
			Not Available：MD300C1、MD300C2、MD300C61、MD300C63	
Comparison Statement			**The applicant device has similar device specifications as the predicate device.**	
Contacting Material		Battery cover	ABS	ABS
		Fingertip Cushion	Medical Silicon gel	Medical Silicon gel
		Enclosure	ABS	ABS
Comparison Statement			**The contacting materials of applicant device are as same as that of the predicate device.**	
Performance Testing	Bench Test		The bench tests include Test for Pulse signal strength Indicator Bar、Pulse rate and SpO2 accuracy test for 3000 cycles Cleaning、Test for Random vibration、wide band and Test according to ISO9919. All the bench test results are provided in ***Performance Testing-Bench***	Meet the requirements of FDA Guidance
	Clinical Test		Conformed to ISO 9919	Conformed to ISO 9919

		Clinical test for device accuracy is conducted by The first Affiliated hospital, Sun Yat-sen university. The clinical test report and protocol are provided in ***Performance Testing-Clinical***			
Electromagnetic Compatibility and Safety	Electrical Safety	Conformed to IEC60601-1. The test results are provided in ***Electromagnetic Compatibility and Electrical Safety***		Conformed to IEC60601-1	
	Electromagnetic Compatibility	Conformed to IEC60601-1-2. The EMC test reports were provided in ***Electromagnetic Compatibility and Electrical Safety***		Conformed to IEC60601-1-2.	
Software		Moderate Level of Concern		Moderate Level of Concern	
		Compliance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.		Compliance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.	
		Risk Management in Compliance with IEC 60601-1-4		Risk Management in Compliance with IEC 60601-1-4	
Biocompatibility	Medical silicone gel	In Vitro Cytotoxicity	No cytotoxic potential	In Vitro Cytotoxicity	No cytotoxic potential
		Skin Irritation Test	No evidence of causing sensitization	Skin Irritation Test	No evidence of causing sensitization

		Animal skin irritation test	No evidence of significant irritation from the test extract to rabbits	Animal skin irritation test	No evidence of significant irritation from the test extract to rabbits
	ABS plastic	In Vitro Cytotoxicity	No cytotoxic potential	In Vitro Cytotoxicity	No cytotoxic potential
		Skin Irritation Test	No evidence of causing sensitization	Skin Irritation Test	No evidence of causing sensitization
		Animal skin irritation test	No evidence of significant irritation from the test extract to rabbits	Animal skin irritation test	No evidence of significant irritation from the test extract to rabbits
Label and Labeling		Compliance with FDA guidance		Compliance with FDA guidance	

3.6 Intended Use

The Fingertip Pulse Oximeters, MD300C series, are portable, non-invasive devices intended for spot checking of arterial hemoglobin oxygen saturation (SpO2) and pulse rate of adult and pediatric patient at hospital (including clinical use in internist/surgery, Anesthesia, and intensive care units).

3.7 Test

Non-clinical Test

The Fingertip Pulse Oximeters MD300C series are designed and tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

- IEC 60601-1 Medical Electrical Equipment – Part1: General requirements for safety.
- IEC 60601-1-2:2007 Medical Electrical Equipment – Part 1: General requirements for safety-2, Collateral Standard: Electromagnetic compatibility – Requirements and tests.
- ISO 9919:2005, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

The Software Validation is in compliance with FDA Guidance for the Content of PreMarket Submissions for Software Contained in Medical Devices.

The compatibility of the skin-contact component material in the finished product meets the requirement of Biocompatibility. The Biological Evaluation Tests are in compliance with the standards of ISO 10993, "Biological Evaluation of Medical Devices".

The list of non-clinical test performed on the proposed device.

No.	Test Name
1	Broad-band Vibration Test
2	Pulse rate and SpO2 Accuracy Test for 3000 cycles' cleaning
3	System Performance Test
4	Shelf life Test
5	Test for Pulse Signal Strength Indicator Bar
6	Performance Test according to ISO 9919
7	Electromagnetic Compatibility Test According to IEC 60601-1-2
8	Electrical Safety Test According to IEC 60601-1
9	Irritation、Sensitization and Cytotoxicity Test according to ISO 10993

The test results indicate that the safety and effectiveness of the proposed devices is identical to that of the predicate device.

Clinical Test

The Fingertip Pulse Oximeters MD300C1 / MD300C2 / MD300CF3/ MD300CF61 / MD300C61 / MD300C63 share the same pulse oximeter sensor and oxygen saturation module. So we considered a clinical test of one of the proposed devices could cover that of other devices. The clinical test of other proposed devices can be exempted. And we conducted clinical test for one of the proposed devices, and the model is MD300C63.

The Clinical Test was conducted according to ISO 9919:2005, Annex EE.2 in the lab of the first affiliated hospital, Sun Yat-sen University. The study protocol was subjected to ISO 9919:2005 Annex EE. Procedures of testing required in EE2 were adopted.

Subjects:

After Institutional Review Board (IRB) approval, 12 healthy adult volunteer subjects (ages 21-31yr, 45-78kg, with light to dark pigmentation) were included in the study conducted to evaluate the SpO_2 accuracy performance.

Methods:

Each system was evaluated during steady state / non-motion conditions with various levels of induced hypoxia resulting in stable oxygen saturation levels between 100% and 70% SaO_2. Arterial blood samples were drawn during simultaneous data collection from the test devices. The blood was immediately analyzed on Reference CO-Oximetry providing functional SaO_2 for the basis of the SpO_2 accuracy comparison.

Adverse events and complications:

There are no adverse events during the clinical test.

Conclusion:

The results of the study provide supporting evidence that the MD300C63 Fingertip Pulse Oximeter is compliance to the accuracy specification claimed by the manufacturer. The Fingertip Pulse Oximeter can be used under steady state / non-motion conditions for the range 70-100%.

3.8 Determination of substantial equivalence

The proposed devices of Finger Pulse Oximeters MD300C series have the same classification information, same indications and intended use, same design principle, similar product design and specifications, same performance effectiveness, performance safety as the predicate device. The differences only exist in display screen、SpO_2 and PR display range、appearance and audible/visual indicator and pulse rate tone modulation functions. These differences are slight and do not influence the effectiveness and safety of the device. According to the non-clinical and clinical test results, the proposed devices are as safe, as effective and perform as well as the predicate device. So the proposed devices are Substantially Equivalent (SE) to the predicate device which is US legally market device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

Beijing Choice Electric Technology Company, Limited
Mr. Lei Chen
Quality Director
North Building 3F, No. 9 Shuangyuan Road,
Badachu Hi-tech Zone, Shijingshan District
Beijing
China 100041

Re: K130947
Trade/Device Name: Fingertip Pulse Oximeter MD300C1, MD300C2, MD300CF3, MD300CF61, MD300C61, and MD300C63
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 30, 2013
Received: September 3, 2013

Dear Mr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 2 Indications for Use Statement

Indications for Use

510(k) Number (if known): K130947

Device Name: Fingertip Pulse Oximeter MD300C1、MD300C2、MD300CF3、MD300CF61、MD300C61、MD300C63

Indications for Use:

The Fingertip Pulse Oximeters, MD300C series, are portable, non-invasive devices intended for spot checking of arterial hemoglobin oxygen saturation (SpO_2) and pulse rate of adult and pediatric patient at hospital (including clinical use in internist/surgery, Anesthesia, and intensive care units).

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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